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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
07/835,964	02/20/92	COATES	J IAF-14
			EXAMINER

12M1/0107  
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ART UNIT	PAPER NUMBER
1202	37
DATE MAILED: 01/07/98	

01/07/98

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

#### OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on OCT 24, 1997

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire THREE month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

- ☒ Claim(s) 2, 23 and 24 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 2, 23 and 24 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

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Applicants response of Oct. 21, 1997 is noted.

The claim in the application are claims 7 and 23 and 24.

It appears that claim 7 were inadvertently not rejected previously, with all of the attention on just what is the structure of BCH 189 and what is the structure of 3TC. See Coates et al., vol. 36, No. 1 pp. 202-205 (June 1992) Antimicrobial Agents and Chemotherapy. *cited to clarify structure.*

Also, See Emory University vs. Glaxo Wellcome Inc. 44 U.S.P.Q. (2nd) No. 6 p. 1407 (+) (11-10-97). It is not inconsistent for this Examiner to reject the present claims over both Liotta '116 and Belleau '407, because it is this Examiner's position that they both claim 3TC, as labeled by the above Coates Article. The last example of Belleau<sup>1407</sup> deals with this cis form (Example 8) and separates it into two isomers. Claim 10 of Belleau 407 claims the present compounds, ~~the~~ claims of Liotta '116 are to the compound and composition noted here. This examiner is aware that claims 23 and 24, here are method claims to treating HIV. However, the utility for these compounds were disclosed for this utility by Belleau et al. as early as June 16, 1989 at the AIDS conference in Montreal. Abstract TCO1 of Belleau suggest replacing the 3' carbon of the furanose ring, see col. 1 of Belleau '407 for

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further structure clarification, with S or O, and have good HIV results. NG PB-21 is described as having the "natural" configuration.

Therefore, since claim 7 is really just a method of making a composition, comprising adding the active ingredient to a carrier, it must be rejected as common knowledge and obvious under 35 U.S.C. 103. Note any of the prior art and common texts, such as, <sup>Remington's</sup> Practice of Pharmacy. Official Notice ~~or~~ Judicial Notice can be easily taken that the method of making the composition is obvious.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 23 and 24 are rejected under 35 U.S.C. 103 as being unpatentable over Belleau '407, which has a Feb. 8, 1989 date. The present compounds are claimed in claim 10 and disclosed in col. 3 as an anti HIV agent. Example 8 is separating the Cis isomer into two more isomers. The addition of the S at the 3' position is shown in formula I of col. 3 as indicated by Belleau in the AID-5

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Conference in Montreal in June 6, 1989, these disclosures all indicate HIV activity would be expected. This is expected because the starting materials with S in the 3' position are known from Belleau U.S. Patent 5,466,806. Note cols. 1 and 2 of Belleau indicate the compounds without the S in the 3' position were known to Balzarini, Mitsuura et al. and Baba et al. to be anti-HIV agents. Therefore, the close structure relationships here would lead to the expectation that the position compound would also be useful against HIV. The suggestion to modify the compounds of Balzarini et al. and Mitsuura in cols. 1-2 of Belleau 407 is in Belleau disclosure there and in the AIDS conference in Montreal. Therefore, it is obvious to one of ordinary skill in the art that the present compounds would be useful against HIV.

Claims 23 and 24 are rejected under 35 U.S.C. 102 and 103 as the exact compounds employed here are claimed in Liotta '116 and their activity against HIV is disclosed. See col. 1 the Klibanov affidavit of 44 U.S.P.Q. (2nd) pp. 1413-14 contents that Liotta '116 was in possession of the (-) enantiomer.

There apparently is a connection between Galaxo and the present assignee, see 44 U.S.P.Q. (2nd) p. 408.

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There is a substantial case of derived knowledge from Balzarini et al., Baba et al. and Mitsuya et al. that the present compounds would be expected to be active against HIV. See the provisions discussion. Liotta knew about it, as can be demonstrated in prior art, disclosure and claims of Liotta U.S. Patent 5,204,466.

The (-) isomer is not unobvious over the racemate. See Eli Lilly vs. Generic Drug Sales 169 U.S.P.Q. 13, previously cited and discussed. Note 44 U.S.P.Q. 2nd at 1411, one would expect the (-) enantiomer to be present and callable into existence, as such, without the (+) by means known in the art.

See Enantiomers, Racemates and Resolutions, Jean Jacques et al., A-Wiley-Interscience publication, John Wiley and from New York (1981).

Belleau et al. at the AIDS conference in Montreal (Abstract TC0.1) indicated the cis (and presumably the (-)) was the natural configuration, and the configuration expected to have the utility. Dr. Storers declarations make it quite clear, and believable, that the present compounds would have the present utility, because of its close structural relationship to AZT and those shown in cols. 1-2 and 3 of Belleau '407, and, therefore, obvious.

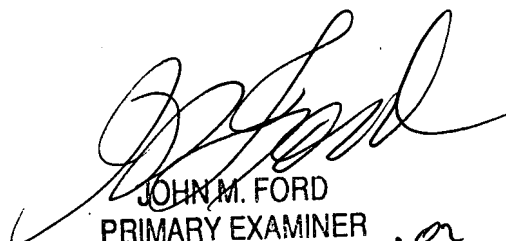
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The Coates Article, previously noted, indicates the Biological activity usually results in a single enantiomer, and that they had separated the (-) and (+) forms. *p. 202*

A facsimile machine has been established in Group 1200, room 4E18. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-3592.

FORD; aco

December 31, 1997

  
JOHN M. FORD  
PRIMARY EXAMINER  
GROUP 120 - ART UNIT *1202*